**510(k) Summary**

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Name and Address of Manufacturer:
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Device Identification:
Trade Name: OIC External Fixation System
Common Name: External fixation components
Classification Name: Single/multiple component metallic bone fixation appliances and accessories
Classification: Class II, 21 CFR 888.3030
Panel: Orthopedic
Product Code: KTT

Indications for Use:
The OIC External Fixation system is intended to be used in adult and pediatric patients for provisional fixation of open and/or unstable fractures in the lower and upper extremities and pelvis. It may also be used for temporary fixation of peri-articular or intra-articular fractures. Additionally, the device can be used on fractures where soft tissue injury or an infected fracture site may preclude the use of other fracture fixation treatments.

Device Description:
The device is used for the external stabilization of bone fractures. It consists of:
Carbon fiber composite bars, 11mm diameter, 100mm to 650mm lengths
Titanium and aluminum combination clamp, 5 & 8 hole pin clamp
Aluminum straight and angled posts
Stainless steel 4mm and 5mm pins, blunt tip and threaded 150mm, 200mm and 250mm lengths, 15mm through 120mm thread lengths.
Stainless steel 5mm transfixing pin, 300mm length
Stainless steel instruments for implantation
The pins are implanted into bone and then they are connected using the clamps, rods and posts to form a rigid construct which holds the bone fragments rigidly in place. The pins are offered in various lengths and thicknesses.

Comparison of Technological Characteristics (Substantial Equivalence):
Predicate devices: K171211 OIC External Fixation System, K082650 Synthes Large External Fixation MR Conditional
The OIC External Fixation System has the following similarities to those which previously received 510(k) concurrence:
· has the same indicated use,
· uses the same operating principle,
· incorporates the same design, and
· incorporates the same or similar materials

Performance Testing:
Magnetic resonance imaging (MRI) compatibility testing was performed on the OIC External Fixation System. Testing shows that the system has acceptable MRI characteristics for the intended uses.

Conclusion:
The OIC External Fixation System described in this submission is, in our opinion, substantially equivalent to the predicate devices.